REMARKS

Claims 28-30 and 37-39 are all the claims pending in the application, prior to the present Amendment.

Applicants undersigned attorney thanks the Examiner, Ms. Royds, for courteously granting the telephone interview of July 22, 2010. The following remarks will discuss the interview and in so doing constitute a Statement of Substance of Interview.

Claim 39 has been objected to for failing to conclude with a period. Applicants have amended claim 39 to add a period at the end of claim 39.

Applicants note that in the Amendment Under 37 C.F.R. § 1.114(c) that was filed on October 19, 2009, applicants had intended to cancel claim 29, but inadvertently did not do so. Applicants have now canceled claim 29.

Claims 28, 30 and 37-39 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

The Examiner states in the Office Action that claim 28 specifies that the fatigue reducing agent to be administered comprises reduced coenzyme Q of the formula (1) and oxidized coenzyme Q of the formula (2), wherein the ratio of reduced coenzyme Q to the total coenzyme Q is 60-100% by weight.

The Examiner states in the Office Action that it is unclear how the ratio of reduced coenzyme Q to the total amount of coenzyme Q can be 100% by weight if the fatigue reducing agent is expressly defined as comprising both a reduced form of coenzyme Q and an oxidized form of coenzyme Q.

The Examiner states in the Office Action that for the purposes of examination, the claims will be interpreted to require that both reduced coenzyme Q and oxidized coenzyme Q are

present in the composition to be administered (i.e., not just reduced coenzyme Q alone if the ratio of reduced coenzyme Q to total coenzyme Q was 100%).

Although applicants disagree with the Examiner's interpretation of the previously presented claim 28 and believe that one of ordinary skill in the art would understand that oxidized coenzyme Q was not present when the amount of reduced coenzyme Q is 100%, applicants have amended claim 28 to even more clearly indicate that claim 28 covers the use of reduced coenzyme Q and oxidized coenzyme Q, and also covers the use of reduced coenzyme Q without the presence of oxidized coenzyme Q. Thus, claim 28 now states that the active ingredient can be reduced coenzyme Q and oxidized coenzyme Q in a specified ratio, or can be reduced coenzyme Q in an amount of 100% based on total coenzyme Q.

During the above telephone interview, the Examiner indicated that the above amendment would overcome the rejection.

In view of the above, applicants request withdrawal of this rejection.

Claims 28, 30 and 37-39 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

The Examiner states in the Office Action that there is insufficient antecedent basis for the term 'the ratio" or the term "the total coenzyme Q" as recited in claim 28, because the preceding text of the claim fails to provide any reference to "a ratio" or "total coenzyme Q" per se.

In response, applicants point out that as stated in the MPEP at 2173.05(a), the failure to provide explicit antecedent basis for terms does not always render a claim indefinite. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite. *Energizer Holdings Inc. v. Int'l Trade Comm'n, 435 F.3d 1366, 77 USPQ2d 1625 (Fed. Cir. 2006)(holding that "anode gel" provided by implication the antecedent basis for "zinc*

anode"); Ex parte Porter, 25 USPQ2d 1144, 1145 (Bd. Pat. App. & Inter. 1992) ("controlled stream of fluid" provided reasonable antecedent basis for "the controlled fluid"). Inherent components of elements recited have antecedent basis in the recitation of the components themselves.

In the present case, since claim 28 refers to reduced coenzyme Q and oxidized coenzyme Q, it is clear that a ratio must exist that defines the relationship between the amounts of reduced coenzyme Q and oxidized coenzyme Q. Accordingly, applicants submit that it is not necessary for claim 28 to provide explicit antecedent basis for the term "the ratio." Nevertheless, applicants have amended claim 28 to now refer to "a ratio."

Similarly, since claim 28 refers to the presence of coenzyme Q in the composition, there is a total amount of coenzyme Q that inherently will be present. Accordingly, applicants submit that it is not necessary for claim 28 to provide explicit antecedent basis for the term "the total coenzyme Q." Nevertheless, applicants have amended claim 28 to refer to "total coenzyme Q."

During the above telephone interview, the Examiner indicated that the above amendments would overcome the rejection.

In view of the above, applicants request withdrawal of this rejection.

Claim 37 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

In response, applicants have canceled claim 37. Accordingly, this rejection is moot.

Claims 28-30 and 38-39 have been rejected under 35 U.S.C. § 103(a) as obvious over WO 2002/092067 to Fuji et al (citing to U.S. Patent Application Publication No. 2004/0115181 (2004) for an English translation) in view of the Wilson et al publication, and further in view of the excerpt from Remington's Pharmaceutical Sciences (Fifteenth Edition, 1980, page 712) for

the reasons of record set forth at p. 3-8 of the previous Office Action dated May 18, 2009, of which said reasons are herein incorporated by reference..

The Examiner appears to agree that applicants have shown unexpected results, but asserts that the results are not commensurate in scope with the breadth of the claims

With respect to the results of Ex. 1, Comparative Ex. 1 , Ex. 2 and Comparative Ex. 2, the Examiner states that these results are not commensurate in scope with what is presently claimed. The Examiner asserts that Ex. 1, Comparative Ex. 1 , Ex. 2 and Comparative Ex. 2 employ either reduced or oxidized coenzyme Q10, but the present claims are directed to the use of a fatigue reducing agent that comprises a reduced coenzyme Q of formula (1) in combination with an oxidized coenzyme Q of formula (2) in a ratio of reduced coenzyme Q to total coenzyme Q of 60-100% by weight.

Thus, the Examiner asserts that Ex. 1, Comparative Ex. 1, Ex. 2 and Comparative Ex. 2 only tested the effect of each component individually (i.e., reduced coenzyme Q10 versus oxidized coenzyme Q10), and failed to determine the effect of the two components in combination as presently claimed.

Applicants point out, however, that the reduced coenzyme Q employed in Examples 1 and 2 contained 1% of oxidized coenzyme Q. See, page 17, lines 11 and 12 of the present specification. Thus, Examples 1 and 2 did, in fact, employ a combination of reduced coenzyme Q and oxidized coenzyme Q.

The Examiner agrees in the Office Action that Example 4 and Comparative Example 4 show that a statistically significant increase was demonstrated on maximum running time in aged rats "that appears to be both unexpected and unpredictable," but has taken the position in the

Office Action that the results fail to establish an unexpected effect commensurate in scope with the presently claimed subject matter.

In particular, the Examiner asserts in the Office Action that the results do not provide a basis for concluding that the full scope of the claimed subject matter would not have been obvious because the results are limited to a combination of reduced coenzyme Q10 and oxidized coenzyme Q10, while the claims subject to this rejection encompass the use of the combination of a reduced coenzyme Q_{1-12} with oxidized coenzyme Q_{1-12}.

In response, applicants have amended the claims to direct them to reduced coenzyme Q10 and oxidized coenzyme Q10, or to 100% reduced coenzyme Q10. Example 4 employed 99% reduced coenzyme Q10 and, therefore, supports unexpected results for 100% reduced coenzyme Q10.

With respect to the amounts, the Examiner has taken the position in the Office Action that the results are insufficient to establish the non-obviousness of amounts wherein the ratio of reduced coenzyme Q to total coenzyme Q ranges from 60-100% by weight.

In response, applicants have amended claim 28 to recite that when reduced coenzyme Q and oxidized coenzyme Q are employed, the ratio of reduced coenzyme Q to total coenzyme Q is not less than 80%, and to recite that the reduced coenzyme Q can be in an amount of 100%. Support for this amendment can be found at page 9, lines 3 to 10 of the specification.

Applicants submit that the results obtained with the exemplified ratio would have been expected to occur over the ratio range set forth in the amended claim 28.

The present invention is characterized in that reduced coenzyme Q10 is mainly effective for reducing fatigue, and therefore, the amount of oxidized coenzyme Q10 contained in reduced

coenzyme Q10 is not substantially important as long as the reduced coenzyme Q10 is present in an amount that is in excess of the amount of the oxidized coenzyme Q10.

Applicants submit that the results of Examples 1 to 4 are clearly commensurate in scope with what is presently claimed and sufficient to establish nonobviousness of the amended claims.

In view of the above, applicants request withdrawal of this rejection.

Claims 28, 30 and 37-39 have been provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent Application No. 11/993,743.

Applicants defer responding to this rejection since the rejection is a provisional rejection and the copending application has not issued as a patent.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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